

DOCKET NO.: 113019.179US1

PATENT/OFFICIAL

in re Application of

Ke-Wen DONG et al.

Serial No. 09/252,828

: Group Art Unit: 1641

Filed: February 19, 1999

: Examiner: Lisa V. Cook

For: RECOMBINANT BIOLOGICALLY ACTIVE HUMAN ZONA PELLUCIDA PROTEIN
3 (hZP3) TO TEST MALE FERTILITY

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached form PTO-1449. It is respectfully requested that the documents be expressly considered during the prosecution of this application, and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

In accordance with 37 C.F.R. § 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search had been made or that information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item, and Applicant reserves the right to prove that the date of publication is in fact different.

11/14/2003 HVUDONG1 00000034 080219 09252828

01 FC:1806 180.00 DA

The fee of \$180.00 pursuant to 37 CFR § 1.17(p) is attached. The Commissioner is authorized to charge any deficiency in any fees pursuant to 37 CFR § 1.17 associated with this communication and to credit any excess payment to Deposit Account No. 08-0219.

Respectfully submitted,

HALE AND DORR LLP


Maria L. Maebius
Registration No. 42,967

1455 Pennsylvania Avenue, NW
Washington, DC 20004

TEL 202.942.8400 MLM/lrm

FAX 202.942.8484

Date: 13 November 2003

\$ 180 is not attached

INFORMATION DISCLOSURE
CITATION IN AN
APPLICATION

(PTO-1449)

ATTY. DOCKET NO.
113019.179US1SERIAL NO.
09/252,828APPLICANT
Ke-Wen DONG et al.FILING DATE
February 19, 1999GROUP
1641

RECEIVED
NOV 18 2003
TECH CENTER 1600/2900

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	4,444,879	04/24/84	Foster et al.			01/29/81

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation
						Yes No

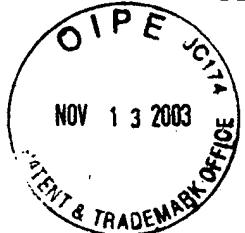
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

Chirgwin, John M., Alan E. Przybyla, Raymond J. MacDonald, and William J. Rutter. 1979. "Isolation of Biologically Active Ribonucleic Acid from Sources Enriched in Ribonuclease." <i>Biochemistry</i> . Vol. 18, No. 24, pp. 5294-5299.
Bleil, Jeffrey D. and Paul M. Wassarman. July 1980. "Mammalian Sperm-Egg Interaction: Identification of a Glycoprotein in Mouse Egg Zonae Pellucidae Possessing Receptor Activity for Sperm." <i>Cell</i> . Vol. 20, pp. 873-882.
Maggio, Edward T. 1980. <i>Enzyme-Immunoassay</i> . Boca Raton, FL: CRC Press, Inc. pp. 186-187.
Dunbar, Bonnie S., Cecilia Liu, and David W. Sammons. 1981. "Identification of the Three Major Proteins of Porcine and Rabbit Zonae Pellucidae by High Resolution Two-Dimensional Gel Electrophoresis: Comparison with Serum, Follicular Fluid, and Ovarian Cell Proteins." <i>Biology of Reproduction</i> . Vol. 24, pp. 1111-1124.
McIlhinney, R. A. J. and Shashikant Patel. March 1983. "Characterization of the Fibronectin Synthesized by Human Germ Cell Tumors." <i>Cancer Research</i> . Vol 43, pp. 1282-1288.
Florman, Harvey M. and Paul M. Wassarman. May 1985. "O-Linked Oligosaccharides of Mouse Egg ZP3 Account for Its Sperm Receptor Activity." <i>Cell</i> . Vol. 41, pp. 313-324.
Fukuda, Michiko N., Anne Dell, Jane E. Oates, and Minoru Fukuda. June 1985. "Embryonal Lactosaminoglycan: The Structure of Branched Lactosaminoglycans with Novel Disialosyl (Sialyl alpha2→9 Sialyl) Terminals Isolated from PA1 Human Embryonal Carcinoma Cells." <i>The Journal of Biological Chemistry</i> . Vo. 260, No. 11, pp. 6623-6631.
Cross, Nicholas L., Patricio Morales, James W. Overstreet, and Frederick W. Hanson. May 1986. "Two Simple Methods for Detecting Acrosome-Reacted Human Sperm." <i>Gamete Research</i> . Vol. 15, pp. 213-226.
Ringuette, Maurice J., Donna A. Sobieski, Steven M. Chamow, and Jurrien Dean. June 1986. "Oocyte-Specific Gene Expression: Molecular Characterization of a cDNA Coding for ZP-3, the Sperm Receptor of the Mouse Zona Pellucida." <i>Proc. Natl. Acad. Sci. USA</i> . Vol. 83, pp. 4341-4345.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

INFORMATION DISCLOSURE CITATION IN AN APPLICATION  (PTO-1449)		ATTY. DOCKET NO. 113019.179US1		SERIAL NO. 09/252,828			
		APPLICANT Ke-Wen DONG et al.					
		FILING DATE February 19, 1999		GROUP 1641			
U.S. PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE	
FOREIGN PATENT DOCUMENTS						Translation	
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Yes	No
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
Burkman, Lani J., Charles C. Coddington, Daniel R. Franken, Thinus F. Kruger, Zev Rosenwaks, and Gary D. Hodgen. April 1988. "The Hemizona Assay (HZA): Development of a Diagnostic Test for the Binding of Human Spermatozoa to the Human Hemizona Pellucida to Predict Fertilization Potential." <i>Fertility and Sterility</i> . Vol. 49, No. 4, pp. 688-697.							
Shabanowitz, R. B. and M. G. O'Rand. 1988. "Characterization of the Human Zona Pellucida from Fertilized and Unfertilized Eggs." <i>J. Reprod. Fert.</i> Vol. 82, pp. 151-161.							
Timmons, T. M. and B. S. Dunbar. 1988. "Antigens of Mammalian Zona Pellucida." <i>Perpectives in Immunoreproduction: Conception and Contraception</i> . New York: Hemisphere Publishing Co. pp. 242-260.							
Wassarman, Paul M. 1988. "Zona Pellucida Glycoproteins." <i>Ann. Rev. Biochem.</i> Vol. 57, pp. 415-442.							
Saling, Patricia M. 1989. "Mammalian Sperm Interaction with Extracellular Matrices of the Egg." <i>Oxf. Rev. Reprod. Biol.</i> Vol. 11, pp. 339-388.							
Sambrook, J., E.F. Fritsch, and T. Maniatis. 1989. <i>Molecular Cloning: A Laboratory Manual</i> . 2 nd Edition. Cold Spring Harbor Laboratory Press. pp. 16.32-16.37.							
Oehninger, Sergio, Anibal Acosta, and Gary D. Hodgen. January 1990. "Antagonistic and Agonistic Properties of Saccharide Moieties in the Hemizona Assay." <i>Fertility and Sterility</i> . Vol. 53, No. 1, pp. 143-149.							
Furukawa, Tatsuhiko, Masayuki Ozawa, Ruo-Pan Huang, and Takashi Muramatsu. March 1990. "A Heparin Binding Protein Whose Expression Increases During Differentiation of Embryonal Carcinoma Cells to Parietal Endoderm Cells: cDNA Cloning and Sequence Analysis." <i>J. Biochem.</i> Vol. 108, No. 2, pp. 297-302.							
Liang, Li-Fang, Steven M. Chamow, and Jurrien Dean. April 1990. "Oocyte-Specific Expression of Mouse Zp-2: Developmental Regulation of the Zona Pellucida Genes." <i>Molecular and Cellular Biology</i> . Vol. 10, No. 4, pp. 1507-1515.							
Kinloch, Ross A., Betina Ruiz-Seiler, and Paul. M. Wassarman. August 1990. "Genomic Organization and Polypeptide Primary Structure of Zona Pellucida Glycoprotein hZP3, the Hamster Sperm Receptor." <i>Developmental Biology</i> . Vol. 142, pp. 414-421.							
Wassarman, Paul M. 1990. "Profile of a Mammalian Sperm Receptor." <i>Development</i> . Vol. 108, pp. 1-17.							
EXAMINER		DATE CONSIDERED					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

INFORMATION DISCLOSURE CITATION IN AN APPLICATION		ATTY. DOCKET NO. 113019.179US1		SERIAL NO. 09/252,828			
(PTO-1449)		APPLICANT Ke-Wen DONG et al.					
		FILING DATE February 19, 1999		GROUP 1641			
U.S. PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE	
FOREIGN PATENT DOCUMENTS						Translation	
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Yes	No
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	Wassarman, P. M. 1990. "Regulation of Mammalian Fertilization by Zona Pellucida Glycoproteins." <i>J. Reprod. Fert., Suppl.</i> Vol. 42, pp. 79-87.						
	1991. "Errata." <i>Developmental Biology</i> . Vol. 145, pp. 203-204.						
	Saling, Patricia M. 1991. "How the Egg Regulates Sperm Function During Gamete Interaction: Facts and Fantasies." <i>Biology of Reproduction</i> . Vol. 44, pp. 246-251.						
	Beebe, Stephen J., Lisette Leyton, Deborah Burks, Motoharu Ishikawa, Tom Fuerst, Jurrien Dean, and Patricia Saling. January 1992. "Recombinant Mouse ZP3 Inhibits Sperm Binding and Induces the Acrosome Reaction." <i>Developmental Biology</i> . Vol. 151, pp. 48-54.						
	Thillai-Koothan, P., Marcel Van Diun, and R. John Aitken. May 1993. "Cloning, Sequencing and Oocyte-Specific Expression of the Marmoset Sperm Receptor Protein, ZP3." <i>Zygote</i> . Vol. 1, pp. 93-101.						
	Lee, Vaughan H., Eric Schwob, Sarvamangala Prasad, Peter Cheung, Therese M. Timmons, Richard Cook, and Bonnie S. Dunbar. June 1993. "Identification and Structural Characterization of the 75-kDa Rabbit Zona Pellucida Protein." <i>The Journal of Biological Chemistry</i> . Vol. 268, No 17, pp. 12412-12417.						
	Liang, Li-Fang and Jurrien Dean. 1993. "Conservation of Mammalian Secondary Sperm Receptor Genes Enables the Promoter of the Human Gene to Function in Mouse Oocytes." <i>Developmental Biology</i> . Vol. 156, pp. 399-408.						
	Varki, Ajit. 1993. "Biological Roles of Oligosaccharides: All of the Theories Are Correct." <i>Glycobiology</i> . Vol. 3, No. 2, pp. 97-130.						
	Barratt, C.L.R., A. Whitmarsh, D.P. Hornby, S. Clements, I.D. Cooke, and H.D.M. Moore. 1994. "Glycosylation of Human Recombinant ZP3 Is Necessary to Induce the Human Acrosome Reaction" (Abstract No. 33). <i>Hum. Reprod.</i> Vol. 9 (Suppl.).						
	Dunbar, B. S., S. Avery, V. Lee, S. Prasad, D. Schwahn, E. Schwob, S. Skinner, and B. Wilkins. 1994. "The Mammalian Zona Pellucida: Its Biochemistry, Immunochemistry, Molecular Biology, and Development Expression." <i>Reprod. Fertil. Dev.</i> Vol. 6, pp. 331-347.						
EXAMINER			DATE CONSIDERED				

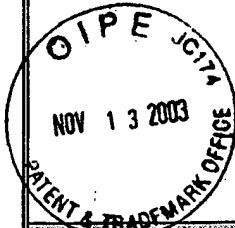
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

INFORMATION DISCLOSURE CITATION IN AN APPLICATION		ATTY. DOCKET NO. 113019.179US1		SERIAL NO. 09/252,828		
(PTO-1449)		APPLICANT Ke-Wen DONG et al.				
		FILING DATE February 19, 1999		GROUP 1641		
U.S. PATENT DOCUMENTS						
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	
FOREIGN PATENT DOCUMENTS						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation
						<input type="checkbox"/> Yes
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
Hinsch, Klaus-Dieter, Elvira Hinsch, Burkhard Meinecke, Edda Töpfer-Petersen, Susanne Pfisterer, and Wolf-Bernhard Schill. 1994. "Identification of Mouse ZP3 Protein in Mammalian Oocytes with Antisera Against Synthetic ZP3 Peptides." <i>Biology of Reproduction</i> . Vol. 51, pp. 193-204.						
Van Duin, Marcel, Jan E.M. Polman, Ingeborg T.M. de Breet, Karin Van Ginneken, Hans Bunschoten, Arijan Grootenhuis, James Brindle, and R. John Aitken. 1994. "Recombinant Human Zona Pellucida Protein ZP3 Produced by Chinese Hamster Ovary Cells Induces the Human Sperm Acrosome Reaction and Promotes Sperm-Egg Fusion." <i>Biology of Reproduction</i> . Vol. 51, pp. 607-617.						
Varki, Ajit. 1994. "[2] Metabolic Radiolabeling of Glycoconjugates." <i>Methods in Enzymology</i> . Vol. 230, pp. 16-32.						
Oehninger, Sergio, Charles C. Coddington, Gary D. Hodgen, and Markku Seppala. February 1995. "Factors Affecting Fertilization: Endometrial Placental Protein 14 Reduces the Capacity of Human Spermatozoa to Bind to the Human Zona Pellucida." <i>Fertility and Sterility</i> . Vol. 63, No. 2, pp. 377-383.						
Burks, D. J., R. Carballada, H. D. M. Moore, and P. M. Saling. July 1995. "Interaction of a Tyrosine Kinase from Human Sperm with the Zona Pellucida at Fertilization." <i>Science</i> . Vol. 269, pp. 83-86.						
Barratt, Christopher L.R. and David P. Hornby. "Induction of the Human Acrosome Reaction by rhuZP3." 1995. <i>Human Sperm Acrosome Reaction</i> . Colloque INSERM/John Libbey Eurotext Ltd. Vol. 236, pp. 105-122.						
Lust, J.A., D.F. Jelinek, K.A. Donovan, L.A. Frederick, B.K. Huntley, J.K. Braaten, and N.J. Maihle. 1995. "Sequence, Expression and Function of an mRNA Encoding a Soluble Form of the Human Interleukin-6 Receptor (sIL-6R)." <i>Curr. Top. Microbiol. Immunol.</i> Vol. 194, pp. 199-206.						
Whitmarsh, A.J., M.J. Woolnough, H.D.M. Moore, D.P. Hornby, and C.L.R. Barratt. 1996. "Biological Activity of Recombinant Human ZP3 Produced <i>in vitro</i> : Potential for a Sperm Function Test." <i>Molecular Human Reproduction</i> . Vol. 2, No. 12, pp. 911-919.						
Franken, Daniel R., Patricio J. Morales, and Ursula F. Habenicht. December 1996. "Inhibition of G Protein in Human Sperm and Its Influence on Acrosome Reaction and Zona Pellucida Binding." <i>Fertility and Sterility</i> . Vol. 66, No. 6, pp. 1009-1011.						
EXAMINER	DATE CONSIDERED					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

INFORMATION DISCLOSURE
CITATION IN AN
APPLICATION

(PTO-1449)



ATTY. DOCKET NO.
113019.179US1

SERIAL NO.
09/252,828

APPLICANT
Ke-Wen DONG et al.

FILING DATE
February 19, 1999

GROUP
1641

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation
						Yes No

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	Brewis, I.A., R. Clayton, C.L.R. Barratt, D.P.J. Hornby, and H.D.M. Moore. 1996. "Recombinant Human Zona Pellucida Glycoprotein 3 Induces Calcium Influx and Acrosome Reaction in Human Spermatozoa." <i>Molecular Human Reproduction</i> . Vol. 2, No. 8, pp. 583-589.
	Chapman, Neil R. and Christopher L.R. Barratt. 1996. "The Role of Carbohydrate in Sperm-ZP3 Adhesion." <i>Molecular Human Reproduction</i> . Vol. 2, No. 10, pp. 767-774.
	Prasad, Sarvamangala V., Brendan Wilkins, Sheri M. Skinner, and Bonnie S. Dunbar. 1996. "Evaluating Zona Pellucida Structure and Function Using Antibodies to Rabbit 55 kDa ZP Protein Expressed in Baculovirus Expression System." <i>Molecular Reproduction and Development</i> . Vol. 43, pp. 519-529.
	Dong, Ke Wen, Ting Fung Chi, Yu Wen Juan, Chih Wei Chen, Zhiyong Lin, Xiao-Qin Xiang, Mary Mahony, William E. Gibbons, and Sergio Oehninger. April 2001. "Characterization of the Biologic Activities of a Recombinant Human Zona Pellucida Protein 3 Expressed in Human Ovarian Teratocarcinoma (PA-1) Cells." <i>Am. J. Obstet. Gynecol.</i> pp. 835-844..

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.